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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,168	06/30/2006	Naohisa Kawamura	0003047USU/3019	9886

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EXAMINER

POCHAS, CHRISTOPHER M

ART UNIT	PAPER NUMBER
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1611

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06/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,168	Applicant(s) KAWAMURA ET AL.	
	Examiner Christopher Pochas	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/28/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Office Action

Priority

1) This application is a 371 of PCT/JP2004/019078 which claims priority to Japanese application 2004-011384. These documents have been received and are in compliance.

Claims

1) Claims 1-10 are pending in the instant application.

Non Final Rejection

35 U.S.C. § 103 Rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman et al., U.S. Patent 5254348, issued October 19th, 1993 and Spada et al., U.S. Patent 5185212, issued February 9th, 1993.

Regarding pending claim 1, U.S. Patent 5254348 (hereafter the 348 patent) discloses a tulobuterol patch with a backing layer (i.e. a support) and a pressure sensitive adhesive. This is disclosed in the first paragraph of column 1 of the 348 patent. A release liner is disclosed in the paragraph of line 5 of column 4 of the 348 patent. Note that the paragraph of line 55 of column 2 discloses that the tulobuterol is within the adhesive matrix. The 348 patent does not teach copolymers of

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acetoacetoxyalkyl (meth)acrylates and vinyl specifically as a pressure sensitive adhesive.

U.S. Patent 5185212 (hereafter the 212 patent) discloses that copolymers of acetoacetoxyalkyl (meth)acrylates and vinyl are useful as pressure-sensitive adhesives. The title and abstract of the 348 patent discloses the acetoacetoxyalkyl acrylate component of the polymer, which reads on the exemplified 2-acetoacetoxyethyl acrylate listed in instant claim 3. The paragraph of line 5 of column 7 of the 212 patent discloses a variety of vinyl monomers which may be incorporated into the polymer of its composition. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to replace the pressure sensitive adhesive of the 348 patent with that of the 212 patent. One would have been motivated to do so because the prior art teaches these as equivalents. One would have had a reasonable expectation of success because acrylic polymers are widely used in transdermal patch adhesives.

Regarding pending claim 2, the paragraph of line 59 of column 3 of the 348 patent discloses the use of plasticizers.

Regarding pending claim 3, claim 4 of the 212 patent discloses acetoacetoxyethyl acrylate.

Regarding pending claim 4, claim 6 of the 212 patent discloses a formula which encompasses these monomers, such as butyl acrylate and methyl methacrylate.

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Regarding pending claim 5, the paragraph of line 59 of column 3 of the 348 patent discloses fatty acid esters of octanol, which include plasticizers of the pending claim.

Regarding pending claim 10, the adhesive described supra is inherently non-aqueous because no water is present.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

5. Claims 6, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman et al., U.S. Patent 5254348, issued October 19th, 1993 and Spada et al., U.S. Patent 5185212, issued February 9th, 1993 as applied to claims 1-5 and 10 above, and further in view of Burton et al., U.S. Patent 5948433, issued September 7th, 1999.

The teachings of the 348 and 212 patents have been set forth above. Neither of these teach isopropyl myristate specifically as a plasticizer, however the 348 patent teaches the use of plasticizers generally.

U.S. Patent 5948433 (hereafter the 433 patent) teaches the use of isopropyl myristate as a plasticizer in a transdermal patch with a pressure sensitive adhesive (column 5, lines 20-40). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use isopropyl myristate as a plasticizer. One would have been motivated to do so and would have had a reasonable expectation of success because it has been used in the prior art as a plasticizer in a transdermal patch adhesive and is therefore an art-recognized equivalent of the plasticizers disclosed in the 348 patent.

Regarding pending claim 8, note that the compositions of Table 1 in column 6 of the 433 patent teach that the plasticizer (mineral oil) is present in amounts within the range of pending claim 8.

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman et al., U.S. Patent 5254348, issued October 19th, 1993 and Spada et al., U.S. Patent 5185212, issued February 9th, 1993 as applied to claims 1-5 and 10 above, and further in view of Higo et al. U.S. Patent 5866157, issued June 1st, 1995.

The teachings of the 348 and 212 patents have been set forth above. Neither of these references teach the specific amount of tulobuterol disclosed in pending claim 9, however the examiner asserts that the examples of the 348 patent would inherently leave tulobuterol present at such an amount.

Should it be found that this is not the case, it would have been *prima facie* obvious to use tulobuterol in this amount, as is disclosed by U.S. Patent 5866157 (hereafter the 157 patent) which reads,

“These physiological active substances may be used alone, or two or more of them may be used together. The physiological active substances may be formulated in an amount from 0.1 to 20% (w/w) based on the total amount of the composition of the adhesive layer. If the amount is less than 0.1% (w/w), a sufficient permeation amount can not be obtained as a matrix type patch formulation, and if the amount exceeds 20% (w/w), the skin irritations such as rubor are observed, and thus it is not preferable.” (line 55 of column 3)

One would have been motivated to use any active ingredient in this amount, which overlaps with the range of pending claim 9, and one would have had a reasonable expectation of success because of the reasons set forth by the 157 patent.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/561751 in view of Hoffman et al., U.S. Patent 5254348, issued October 19th. The teachings of the 348 patent have been discussed supra. The 348 patent does not disclose the specific pressure sensitive adhesive nor the specific plasticizers of the instant claims, however it does disclose the use of pressure sensitive adhesives and plasticizers generally.

The copending application, however, does disclose the use of the plasticizers and pressure sensitive adhesives of the instant claims. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the pressure sensitive adhesives and plasticizers of the copending application. One would have been motivated to do so and would have had a reasonable expectation of success, because the copending application suggests the use of these adhesives and plasticizers in a medical tape for delivering drugs.

The copending application discloses the use of the pressure sensitive adhesive

This is a provisional obviousness-type double patenting rejection.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Pochas whose telephone number is (571)270-7722. The examiner can normally be reached on Monday to Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CMP/

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611